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| 10/728,033  | 12/04/2003  | Stephen F. Badylak   | 3220-73985          | 8358             |
| 23643   | 7590        | 09/11/2006           | EXAMINER            |                  |
| BARNES & THORNBURG LLP<br>11 SOUTH MERIDIAN<br>INDIANAPOLIS, IN 46204 |             |                      | SCHUBERG, LAURA J   |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1651                |                  |

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/728,033

Applicant(s)

BADYLAK, STEPHEN F.

Examiner

Laura Schuberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 1 and 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/13/2005</u> | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Claim Objections***

Claims 1 and 7 are objected to because of the following informalities:

Claim 1 recites the limitation "administering to the patient" in line 2. There is insufficient antecedent basis for this limitation in the claim. The line should read "administering to a patient". Appropriate correction is required.

With regard to claim 7, there appears to be a term missing from line 2 after the term "surgically". For examination purposes the missing term is interpreted to be "implanting". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Badylak (WO 98/25637).

Claim 1 is drawn to a method for inducing the repair of body wall tissues comprising administering to a patient a graft composition comprising basement membrane of a warm-blooded vertebrate in an effective amount to induce the repair of the body wall tissue at the site of administration of the graft. Dependent claims include wherein the graft is multi-layered and formed from two or more layers of liver basement membrane, wherein the layers of liver basement membrane are up to about 2000  $\mu\text{m}$ ,

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wherein the graft is fluidized and administered by injection, wherein the basement membrane is in sheet form and administered by surgically implanting the graft, wherein the basement membrane is in the form of a gel, wherein the basement graft is in powder form.

Badylak ('637) teaches the use of tissue graft composition comprising liver basement membranes of a warm-blooded vertebrate for the repair of damaged or diseased tissues (page 2 lines 1-6)(claim 1). The graft composition can be implanted or fluidized and injected into a host to contact damaged or defective tissues and induce repair or replacement of the tissues (page 2 lines 6-8)(claims 6 and 7). Wherein the composition is in the form of a powder (page 4 line 22)(claim 9), sheet or gel (page 10 lines 20-21)(claims 7 and 8) is taught as well as wherein the composition is in a multilayered configuration (page 6 line 31)(claim 3) with sheets or strips having a thickness of up to about 500  $\mu$  (page 17 line 14)(claim 4). Since the term body wall is not explicitly defined by Applicant and only described as including various differentiated tissue types including connective tissue and skeletal muscle (page 1), the term "body wall" must be given its broadest reasonable interpretation. Since the reference teaches that the repair or replacement of damaged tissue includes connective tissue such as muscle and skin (page 6 line 9) and these tissues are found on the walls of the body and also meet the description of tissues included in the body wall as described by Applicant, the reference is interpreted as teaching the treatment of body wall tissue as well. Thus, the reference anticipates Applicant's claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak (WO 98/25637) in view of Patel et al (US 5,955,110).

Claims 1, 3, 4, 6-9 are drawn to the method as described above.

Claim 2 is drawn to the method of claim 1 wherein the body wall tissue being repaired comprises the abdominal wall.

Claim 5 is drawn to the method of claim 4 wherein the graft composition is formed as a multilayered homolaminate construct.

Badylak ('637) teaches the use of tissue graft composition comprising liver basement membranes of a warm-blooded vertebrate for the repair of damaged or diseased tissues (page 2 lines 1-6). The graft composition can be implanted or fluidized and injected into a host to contact damaged or defective tissues and induce repair or replacement of the tissues (page 2 lines 6-8). Wherein the composition is in the form of a powder (page 4 line 22), sheet or gel (page 10 lines 20-21) is taught as well as wherein the composition is in a multilayered configuration (page 6 line 31) with sheets or strips having a thickness of up to about 500  $\mu$  (page 17 line 14).

Badylak ('637) does not specifically teach wherein the body wall tissue to be repaired comprises the abdominal wall or wherein the graft composition is formed as a multilayered homolaminate construct.

Patel teaches a multilayered submucosal graft construct for use in hernia repair, gastroschisis repair (congenital stomach defects) and other types of body wall repairs that require larger sheets of graft material (column 1 lines 60-65). Small intestinal tissue is taught as the source of the submucosal tissue (column 3 lines 26-27). Patel also teaches that advantageously, both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23).

In addition, Badylak ('637) teaches that basement membrane prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue. The reference

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also states that liver basement membrane can be substituted in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). These applications would all be required for the repair of the body wall. Wherein the construct is taught to have multiple layers at the opposite ends (thus forming a heterolaminate construct) to provide reinforcement for attachment to physiological structures such as bone, tendon, ligament, cartilage and muscle (page 6 line 32- page 7 line 4) is also taught to be an optional embodiment since the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

Therefore, one of ordinary skill in the art would have been motivated to use the invention of Badylak ('637) for the repair of the abdominal wall because Patel teaches that a multilayered submucosal graft can be used in hernia repair and other applications that would include the abdominal wall and because Badylak ('637) also teaches that liver basement membrane can be used in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) reports that basement membranes prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue (page 1 lines 15-20).

In addition, one of ordinary skill in the art would have been motivated to use the multilayered homolaminate construct because Patel teaches that both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23) and Badlak ('637) teaches that heterolaminar constructs (those with extra layers at the ends) are preferable for reinforcement for attachment to bone and other structures (page 7 line 2) and thus would not be required when used for abdominal wall repair. A homolaminate construct would be an obvious choice for repair of the abdominal wall repair since attachment to bones, tendons, ligaments, cartilage and muscle would not be required (only attachment to the body wall) and a step would be saved by not having to form the additional layers on the ends as required by the heterolaminar construct. One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) teaches that the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.



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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24 and 25 of copending Application No. 10/755,386 in view of Patel et al (US 5,955,110) and Badylak (WO 98/25637). Although the conflicting claims are not identical, they are not patentable distinct from each other because the copending application is drawn to a method for inducing the formation of endogenous tissue at a site in need in a warm-blooded vertebrate comprising implanting a graft composition comprising gelled liver basement membrane tissue of a warm-blooded vertebrate at the site in need in an amount effective and wherein the composition is implanted surgically.

The copending application does not include wherein the body wall or abdominal wall is the site of repair or wherein the construct is multilayered, the thickness of the layers or wherein the construct is formed as a homolaminate. Wherein the construct is in a sheet form and surgically implanted or in powder form is also not included.

Patel teaches a multilayered submucosal graft construct for use in hernia repair, gastroschisis repair (congenital stomach defects) and other types of body wall repairs

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that require larger sheets of graft material (column 1 lines 60-65). Small intestinal tissue is taught as the source of the submucosal tissue (column 3 lines 26-27). Patel also teaches that advantageously, both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23).

Badylak ('637) teaches the use of tissue graft composition comprising liver basement membranes of a warm-blooded vertebrate for the repair of damaged or diseased tissues (page 2 lines 1-6). The graft composition can be implanted or fluidized and injected into a host to contact damaged or defective tissues and induce repair or replacement of the tissues (page 2 lines 6-8). Wherein the composition is in the form of a powder (page 4 line 22), sheet or gel (page 10 lines 20-21) is taught as well as wherein the composition is in a multilayered configuration (page 6 line 31) with sheets or strips having a thickness of up to about 500  $\mu$  (page 17 line 14). Badylak ('637) also teaches that basement membrane prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue. The reference also states that liver basement membrane can be substituted in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). These applications would all be required for the repair of the body wall. Wherein the construct is taught to have multiple layers at the opposite ends (thus

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forming a heterolaminate construct) to provide reinforcement for attachment to physiological structures such as bone, tendon, ligament, cartilage and muscle (page 6 line 32- page 7 line 4) is also taught to be an optional embodiment since the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

Therefore, one of ordinary skill in the art would have been motivated to use the method of the copending application for the repair of the abdominal wall because Patel teaches that a multilayered submucosal graft can be used in hernia repair and other applications that would include the abdominal wall and because Badylak ('637) also teaches that liver basement membrane can be used in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) reports that basement membranes prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotrophic properties similar to that which had been reported for intestinal submucosal tissue (page 1 lines 15-20).

In addition, one of ordinary skill in the art would have been motivated to use the multilayered homolaminate construct because Patel teaches that both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23) and Badylak ('637) teaches that

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heterolaminar constructs (those with extra layers at the ends) are preferable for reinforcement for attachment to bone and other structures (page 7 line 2) and thus would not be required when used for abdominal wall repair. A homolaminate construct would be an obvious choice for repair of the abdominal wall repair since attachment to bones, tendons, ligaments, cartilage and muscle would not be required (only attachment to the body wall) and a step would be saved by not having to form the additional layers on the ends as required by the heterolaminar construct. The use of different forms such as multilayered, powder and sheet would have been obvious to include in the copending application because Badylak and Patel teach that these are suitable forms for the construct. The thickness of the layers of the construct would have been a matter of routine optimization depending on the thickness of the body wall in need of repair. One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) teaches that the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

This is a provisional obviousness-type double patenting rejection.

Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 9 of U.S. Patent No. 6,793,939 in view of Patel et al (US 5,955,110) and Badylak (WO 98/25637). Although the conflicting claims are not identical, they are not patentable distinct from each other because the copending application is drawn to a method for inducing the formation of endogenous tissue at a site in need in a warm-blooded vertebrate comprising implanting a graft

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composition comprising an extracellular matrix consisting essentially of basement membrane of liver tissue of a warm blooded vertebrate in an amount effective to induce endogenous tissue growth at the site of administration. Wherein the basement membrane is fluidized and administered by injection and administered by surgically implanting and wherein the liver tissue is in sheets having a thickness of up to about 500  $\mu$  are also included.

The copending application does not include wherein the body wall or abdominal wall is the site of repair or wherein the construct is multilayered, or wherein the construct is formed as a homolaminate. Wherein the construct is in a sheet form and surgically implanted or in powder form is also not included.

Patel teaches a multilayered submucosal graft construct for use in hernia repair, gastroschisis repair (congenital stomach defects) and other types of body wall repairs that require larger sheets of graft material (column 1 lines 60-65). Small intestinal tissue is taught as the source of the submucosal tissue (column 3 lines 26-27). Patel also teaches that advantageously, both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23).

Badylak ('637) teaches the use of tissue graft composition comprising liver basement membranes of a warm-blooded vertebrate for the repair of damaged or diseased tissues (page 2 lines 1-6). The graft composition can be implanted or fluidized and injected into a host to contact damaged or defective tissues and induce repair or

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replacement of the tissues (page 2 lines 6-8). Wherein the composition is in the form of a powder (page 4 line 22), sheet or gel (page 10 lines 20-21) is taught as well as wherein the composition is in a multilayered configuration (page 6 line 31) with sheets or strips having a thickness of up to about 500  $\mu$  (page 17 line 14). Badylak ('637) also teaches that basement membrane prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue. The reference also states that liver basement membrane can be substituted in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). These applications would all be required for the repair of the body wall. Wherein the construct is taught to have multiple layers at the opposite ends (thus forming a heterolaminate construct) to provide reinforcement for attachment to physiological structures such as bone, tendon, ligament, cartilage and muscle (page 6 line 32- page 7 line 4) is also taught to be an optional embodiment since the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

Therefore, one of ordinary skill in the art would have been motivated to use the method of the copending application for the repair of the abdominal wall because Patel teaches that a multilayered submucosal graft can be used in hernia repair and other applications that would include the abdominal wall and because Badylak ('637) also teaches that liver basement membrane can be used in most, if not all, of the

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applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) reports that basement membranes prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue (page 1 lines 15-20).

In addition, one of ordinary skill in the art would have been motivated to use the multilayered homolaminate construct because Patel teaches that both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23) and Badylak ('637) teaches that heterolaminar constructs (those with extra layers at the ends) are preferable for reinforcement for attachment to bone and other structures (page 7 line 2) and thus would not be required when used for abdominal wall repair. A homolaminate construct would be an obvious choice for repair of the abdominal wall repair since attachment to bones, tendons, ligaments, cartilage and muscle would not be required (only attachment to the body wall) and a step would be saved by not having to form the additional layers on the ends as required by the heterolaminar construct. The use of different forms such as multilayered, powder and sheet would have been obvious to include in the copending application because Badylak and Patel teach that these are suitable forms for the construct. One of ordinary skill in the art would have had a reasonable expectation of

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success because Badylak ('637) teaches that the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

### ***Conclusion***

No claims are allowed.

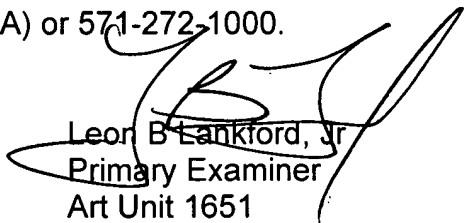
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is 571-272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leon B. Lankford, Jr.  
Primary Examiner  
Art Unit 1651

Laura Schuberg